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United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

AUG - 1 2008

Robert T. Hrubiec, Ph.D, J.D. Cephalon, Inc. 41 Moores Road P.O. Box 4011 Frazer, PA 19300 In Re: Patent Term Extension Application for U.S. Patent No. 4,927,855

Dear Dr. Hrubiec:

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,927,855 for a period of 282 days. This second interim extension under 35 U.S.C. § 156(e)(2) is for less than one year so that any subsequent interim extensions under 35 U.S.C. § 156(e)(2) will extend the term of the patent from the original expiration date of the patent, May 22, 2007.

While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary till@uspto.gov.

Mary C. Till Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner

for Patent Examination Policy

cc: Office of Regulatory Policy

HFD-7

5600 Fishers Lane (Rockwall II Rm 1101)

Rockville, MD 20857

RE: NUVIGILTM (armodafinil)

FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Cephalon Inc.

Request for Interim Patent Term Extension

U.S. Patent No. 4,927,855

ORDER GRANTING

INTERIM EXTENSION

Cephalon, Inc., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, filed a second application under 35 U.S.C. § 156(e)(2) for interim extension of U.S. Patent No. 4,927,855 on July 1, 2008. The previously extended term of the patent is due to expire on August 13, 2008. The patent claims the active ingredient armodafinil in the human drug product NUVIGIL™ and a method of use of said product which was approved by the Food and Drug Administration for commercial marketing or use on June 15, 2007. An extension of 1,066 days from the original expiration date was requested in an application for patent term extension under 35 U.S.C. § 156 filed on July 27, 2007.

The initial USPTO review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because the extended term of the patent will expire on August 13, 2008, before a certificate of extension can be issued, further interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,927,855, is granted for an additional period of 282 days to further extend the patent from the extended expiration date of August 13, 2008, until the new extended expiration date, May 22, 2009.

July 38, 2008

Date

Jon W. Dudaş

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office